§ 520.2261 Sulfamethazine sodium oral dosage forms.

§ 520.2261a Sulfamethazine solution.

(a) *Sponsors.* See Nos. 000010 and 061623 in § 510.600(c) of this chapter for use of a 12.5-percent sulfamethazine sodium solution.

(b) *Related tolerances in edible products.* See § 556.670 of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer in drinking water to provide: Cattle and swine 112.5 milligrams of sulfamethazine sodium per pound of body weight per day on the first day and 56.25 milligrams per pound of body weight on subsequent days; Chickens, 61 to 89 milligrams of sulfamethazine sodium per pound of body weight per day, and turkeys 53 to 130 milligrams of sulfamethazine sodium per pound of body weight per day, depending upon the dosage, age, and class of chickens or turkeys, ambient temperature, and other factors.

(2) *Indications for use.* For treatment and control of diseases caused by organisms sensitive to sulfamethazine.

(i) *Beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*Escherichia coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*Fusobacterium necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.).

(ii) *Swine.* Treatment of porcine colibacillosis (bacterial scours) (*Escherichia coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Chickens and turkeys.* In chickens for control of infectious coryza (*Avibacterium paragallinarum*), coccidiosis (*Eimeria tenella*, *Eimeria necatrix*), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*). In turkeys for control of coccidiosis (*Eimeria meleagrimitis*, *Eimeria adenoeides*). Medicate as follows: Infectious coryza in chickens, medicate for 2 consecutive days; acute fowl cholera and pullorum disease, in chickens, medicate for 6 consecutive days; coccidiosis, in chickens and turkeys, medicate as in paragraph (c) of this section, then reduce amount of medication to one-half for 4 additional days.

(3) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication from cattle, chickens, and turkeys 10 days prior to slaughter for food. Withdraw medication from swine 15 days before slaughter for food. Do not medicate chickens or turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days in cattle or swine. Medicated cattle, swine, chickens, and turkeys must actually consume enough medicated water which provides the recommended dosages. Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

(d) *NAS/NRC status.* The conditions of use specified in this section have been reviewed by NAS/NRC and are found effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

[47 FR 25322, June 11, 1982, as amended at 47 FR 25735, June 15, 1982; 67 FR 78355, Dec. 24, 2002; 70 FR 32489, June 3, 2005; 74 FR 36112, July 22, 2009; 75 FR 10166, Mar. 5, 2010; 76 FR 17337, Mar. 29, 2011]

§ 520.2261b Sulfamethazine powder.

(a) *Specifications.* A soluble powder composed of 100 percent sulfamethazine sodium.

(b) *Sponsors.* See Nos. 000010 and 061623 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.670 of this chapter.

(d) *Conditions of use*—(1) *Chickens*—(i) *Amount.* Administer in drinking water to provide 58 to 85 milligrams (mg) per pound (/lb) of body weight per day.

(ii) *Indications for use.* For control of infectious coryza (*Haemophilus gallinarum*), coccidiosis (*Eimeria tenella*,

E. necatrix), acute fowl cholera (*Pasteurella multocida*), and pullorum disease (*Salmonella pullorum*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate chickens producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated chickens must actually consume enough medicated water which provides the recommended dosages.

(2) *Turkeys*—(i) *Amount.* Administer in drinking water to provide 50 to 124 mg/lb of body weight per day

(ii) *Indications for use.* For control of coccidiosis (*E. meleagrimitis*, *E. adenoeides*).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Do not medicate turkeys producing eggs for human consumption. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms. Medicated turkeys must actually consume enough medicated water which provides the recommended dosages.

(3) *Swine*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use.* For treatment of porcine colibacillosis (bacterial scours) (*E. coli*), and bacterial pneumonia (*Pasteurella* spp.).

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 15 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated swine must actually consume enough medicated water which provides the recommended dosages.

(4) *Cattle*—(i) *Amount.* Administer in drinking water, or as a drench, to provide 108 mg/lb of body weight on the first day and 54 mg/lb of body weight per day on the second, third, and fourth days of administration.

(ii) *Indications for use in beef and nonlactating dairy cattle.* Treatment of bacterial pneumonia and bovine respiratory disease complex (shipping fever complex) (*Pasteurella* spp.), colibacillosis (bacterial scours) (*E. coli*), necrotic pododermatitis (foot rot) (*Fusobacterium necrophorum*), calf diphtheria (*F. necrophorum*), acute mastitis (*Streptococcus* spp.), and acute metritis (*Streptococcus* spp.)

(iii) *Limitations.* Add the required dose to that amount of water that will be consumed in 1 day. Consumption should be carefully checked. Have only medicated water available during treatment. Withdraw medication 10 days prior to slaughter for food. Treatment of all diseases should be instituted early. Treatment should continue 24 to 48 hours beyond the remission of disease symptoms, but not to exceed a total of 5 consecutive days. Medicated cattle must actually consume enough medicated water which provides the recommended dosages.

[71 FR 70303, Dec. 4, 2006, as amended at 75 FR 10166, Mar. 5, 2010]

§ 520.2280 Sulfamethizole and methenamine mandelate tablets.

(a) *Specifications.* Each tablet contains 250 milligrams of sulfamethizole and 250 milligrams of methenamine mandelate.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is indicated for the treatment of urinary tract infections in dogs and cats such as cystitis, nephritis, prostatitis, urethritis, and pyelonephritis. It is also used as an aid in the management of complications resulting from surgical manipulations of the urinary tract such as removal of calculi from the